The Restriction Requirement

The Examiner has made a restriction requirement and has identified two groups as follows:

Group I - recited in claims 5-7 and 21-26.

Group II - recited in claims 19 and 20.

During the phone interview the applicant's attorney told the Examiner that Group I would be elected for further prosecution with a traverse of the requirement. The election of Group I is confirmed. This requirements for restriction are respectfully traversed.

The MPEP states the following with regard to stating a prima facie case of restriction between patentably distinct inventions:

> "There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> 1) The inventions must be independent (see MPEP 802.01, 806.04, 808.01) **or distinct as claimed** (see MPEP 806.05-806.05(i)); and
>
> 2) There must be a **serious burden on the examiner** if restriction is not required (see MPEP 803.02, 806.04(a) - 806.04(j), 808.01(a) and 808.02).
>
> GUIDELINES
>
> Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the requirement in most cases. **Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement**...For purposes of the initial requirement a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02." (MPEP 803)

All of the claims recite related inventions in that each relates to a novel protein, H4-1BB. The Examiner did not make a prima facie case to support a restriction requirement. Both criteria for restriction must be established and the Examiner has not alleged nor shown any burden in searching the claimed inventions.

All of the inventions would include overlapping searches. A method of producing H4-1BB would be relevant for claims to the H4-1BB and likewise claims to H4-1BB would be relevant to methods of producing the protein. Even if some of the inventions would be classified separately, a thorough search of the prior art for any one of the inventions would include the classes and subclasses of the other inventions.

The Applicant requests that the restriction requirement be withdrawn.

The Objections Under 37 CFR §1.821

All of the Examiner's suggestions for complying with 37 CFR §1.821 have been included in the amendments made above except that the Examiner referred to a need for a reference to a SEQ ID NO on page 11. The applicant's attorney did not find a place on page 11 where a reference to the sequence listing should be made, however, on page 7 a reference to the sequence listing was added. The applicant has made a good faith attempt to overcome the objections.

The Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 7, 21, 23-26 under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

Claims 7 and 23 and 24 have been canceled herein.

Claims 21 and 24 both claim a human 4-1BB and recite a limitation for an identifying portion of the sequence. In both cases the Examiner ignores the limitation that the isolated protein must be a human 4-1BB protein. In other words, claims 21 and 24 should be interpreted to only include proteins that have the biological activity of human 4-1BB. In each case the portions of the sequences are recited as means of identifying the protein. The specification describes in great detail the biological activity of human 4-1BB, thus no undue

experimentation is required. The amendments herein are believed to have overcome the other reasons for the rejection of each of these claims.

Claims 25 and 26 recite pharmaceutical compositions of soluble H4-1BB. The specification states that H4-1BB can be used to stimulate B-cells expressing H4-1BB ligands. (see bottom of page 4-top of page 5). As the Examiner states, pharmaceutical compositions consisting of secreted forms of lymphocytic proteins are common in the art. One skilled in the art would know how to formulate a composition including H4-1BB for inducing B-cell proliferation.

In view of the foregoing, the applicant requests that the rejection be withdrawn.

The Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 20, 25 and 26 were rejected under 35 U.S.C. §112, second paragraph. This rejection is respectfully traversed.

Claim 20 was canceled from this application in the preliminary amendment. The examiner also discusses claim 24, however, the objectionable language was removed by the amendment made herein.

Claims 25 and 26 were amended to delete the words "an effective amount" to overcome this rejection.

In view of the foregoing, the applicant requests that the rejection be withdrawn.

The Examiner objected to claim 6 being dependent upon a rejected claims, however, claim 6 is independent. No prior art rejections were made. An additional information disclosure statement was filed on May 2, 1996 which was not considered by the Examiner prior to the office action dated April 19, 1996.

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

Respectfully Submitted:

By: _____

Christopher A. Michaels, Reg. No. 34,390
Attorney for Applicant

BARNARD, BROWN & MICHAELS, P.C.
306 E. State St., Ste. 220
Ithaca, NY 14850
(607) 273-1711
(607) 273-2609 (fax)

Dated: July 19, 1996